EXHIBIT 503

From: Ella_David/Glenview/Watson
Sent: Wednesday, September 22, 2004 2:34 PM
To: JoAnne_Wobeser/Morristown/Watson%Watson; Darlene_Grimm/Corona/Watson%Watson; Suzette_Guzman/Corona/Watson%Watson
Cc: Mary_Woods/Corona/Watson%Watson; Eileen_Mesis/Morristown/Watson%Watson; Michael_Kelly/Glenview/Watson%Watson
Subject: cSOP Training
Attachments: OPDCC 05 Complaints and Medical Inquiries.doc; OPD Call Center Index Guide.xls; OPDCSS 01 DEA Registration Verification.doc; OPDCC 02 Sample Fulfillment.doc; OPDCC 03 Suspicious Orders of Controlled Drugs.doc; OPDCSS 04 Process Controls for Sale and Distribution of Pharmaceutical_ Products.doc; Call Center OPD Signature Training Log.doc

Importance: High

Please copy the following cSOP conversion to be distributed with the ones below. This OPD need only to be distributed. Training Signature log already exist. My suggestion would be to distribute along with one below, on a determined date for training set by Eileen. It will be maintain under the same tab.

(See attached file: OPDCC 05 Complaints and Medical Inquiries.doc)

---------- Forwarded by Ella David/Glenview/Watson on 09/22/2004 04:25 PM ----------

Ella David 09/22/2004 04:05 PM

WATSON Pharmaceuticals, Inc.

To: Eileen Mesis/Morristown/Watson@Watson, Mary Woods/Corona/Watson@Watson, Michael Kelly/Glenview/Watson@Watson
cc: JoAnne Wobeser/Morristown/Watson@Watson, Suzette Guzman/Corona/Watson@Watson

Subject: cSOP Training

Please find attached cSOPs converted into OPDs for Call Center Operation. Training on these OPDs will be done as follows:

- Mary & Eileen will do all Call Center training with the exception of Glenview Trade TeleSales..
- Eileen will be responsible for Morristown,
- Mary & Eileen will be responsible for all Call Center personnel including Corona Trade TeleSales.
- Trade TeleSales will be trained by Ella. Trade TeleSales will not be training on OPDCC Sample Fulfillment.
- Date of training still pending at all sites.

The OPDs will be maintained in the corporate training binders / blue tab titled OPD - Call Center Dept. This was formally know as the cSOP blue tab. Not to worry I have personnel working on the revision as we speak.
Please find attached signature logs to be completed at the end of training. By cc to Joanne, please secure copies of all 5 attachments and Index Guide for all Call Center personnel located at the Morristown facility. Also, please secure 1 copy of the training signature log for Eileen to be completed by the Call Center personnel in Morristown. The training date will be established by Eileen.

Mary & Eileen can designate who will be responsible for copies at the Corona site.

Please submit as soon as possible your training dates. Upon completion, please remember the distribution process for the training signature log noted on the bottom of the form. Feel free to contact me with any questions.

OPDs and Index Guide

(See attached file: OPD Call Center Index Guide.xls)(See attached file: OPDCSS 01 DEA Registration Verification.doc) (See attached file: OPDCC 02 Sample Fulfillment.doc)(See attached file: OPDCC 03 Suspicious Orders of Controlled Drugs.doc)(See attached file: OPDCSS 04 Process Controls for Sale and Distribution of Pharmaceutical Products.doc)

Training Signature Log

(See attached file: Call Center OPD Signature Training Log.doc)

A Watson Pharma, Inc.

Call Center Operations
Call Center Operational Procedure

PROCEDURE:	**DEA Registration Verification**		
WRITTEN BY:	Judy Callahan	**DATE:**	May 3, 2004
Call Center Policy Number:	OPDCC 507509-01.00	**Effective Date**	May 3, 2004
REVISION WRITTEN BY:		**REVISION DATE:**	
Supersedes CC Policy #	CC 1003.00	**CC Policy Date:**	09/03
cSOP Reference #	cSOP 11-003	**cSOP Ref. Date:**	May 3, 2004

I. **Purpose:** To assure compliance with DEA Regulations pertaining to the distribution of controlled drugs.

II. **Scope:** This procedure applies to Call Center with regards to all controlled drugs distributed by Watson Laboratories, Inc. and its Subsidiaries.

DOCUMENT REFERENCES:

Document Number	Document Title
CSOP 13-002	Controlled Substance Schedule II Customer Order Processing
CSOP 13-003	Controlled Substance Schedule II Order Form maintenance & Control
OPD 80-444-CC-CMT	Customer Master / Change CAM & CAM
CTMAN-80-045-CC-LEM	License Entry and Maintenance

ATTACHMENTS:

Document Number	Document Title
N/A	N/A

DEFINITIONS:

•	CSR	Customer Service Representative
•	DEA	Drug Enforcement Agency
•	NTIS	National Technical Information Services
• **A**	DC	Distribution Center – A warehouse facility providing regional Watson product inventory and distribution services.

III. Procedure:

1.0 Verification of DEA Registration

Responsibility	Action	
License Administrator	**1.1**	Current information is to be maintained on the registration status of all customers ordering controlled drugs. Note: DEA License Information is also maintained at the DCs, see CSOP 13-002 Controlled Substance Schedule II Customer Order processing, CSOP 13-003 Controlled Substance Schedule II Order Form Maintenance and Control.

A Watson Pharma, Inc.

Call Center Operations
Call Center Operational Procedure

PROCEDURE:	**DEA Registration Verification**		
WRITTEN BY:	Judy Callahan	**DATE:**	May 3, 2004
Call Center Policy Number:	OPDCC 507509-01.00	**Effective Date**	May 3, 2004

1.2 An active customer list will be maintained. This file contains the Customers Name, Address, DEA number, Approved Schedules, and Watson account number. The expiration date associated with the DEA license is maintained in the customer master file.

Note: See also:

- OPD 80-444-CC-CMT, Customer Master / Change CAM & CAM for maintenance of account integrity.
- CTMAN-80-045-CC-LEM, License Entry and Maintenance, contains instructions on the license maintenance process in the SAP system.

1.3 The list is to be updated by written request to the customer approximately 30 days prior to the expiration date of the current registrations.

1.4 Copies of the DEA certificate will be maintained in a DEA registration number file.

1.4.1 If the customer declines to send a photocopy, the required information will be obtained verbally. After we receive the DEA number verbally, an internet search to the NTIS (National Technical Information Services) will be conducted to locate the record of the DEA in question. Once located, a copy of the file will be printed and filed.

1.5 Report to a supervisor if there is a reason to question the validity of a customer's registration. DEA must be contacted for verification and no controlled drugs will be shipped until registration is verified.

1.6 If the DEA is contacted by phone for verification of registration, a written record of the conversation will be files with the DEA license.

2.0 DEA License Discrepancies

Responsibility	**Action**	
Order Processing Representative	**2.1**	If there is a DEA License discrepancy, information regarding the discrepancy or change will be emailed to the Licensing Administrator for review and approval.
License Administrator	**2.2**	The license administrator will investigate the discrepancy and approve a resolution. All communication with the customer regarding license discrepancies are via the License Administrator. Corrections will be communicated to the CSR via email.
	2.3	The license Administrator will communicate any necessary corrections with the customer.
Sales Administration Management	**2.4**	If any further action is required Sales Administration Management will be notified.

A Watson Pharma, Inc.

Call Center Operations
Call Center Operational Procedure

PROCEDURE:	**Sample Fulfillment**		
WRITTEN BY:	Judy Callahan	**DATE:**	May 3, 2004
Call Center Policy Number:	OPDCC 507509-02.00	**Policy Effective Date**	May 3, 2004
REVISION WRITTEN BY:		**REVISION DATE:**	
Supersede CC Policy #	NA	**CC Policy Date:**	NA
cSOP Reference #	cSOP 11-005	**cSOP Ref. Date**	May 3, 2004

I. **Purpose:** To provide a uniform procedure following the Prescription Drug Marketing Act (PDMA) and governing Watson Pharmaceuticals', Inc. policy for the fulfillment of direct mail and common carrier samples.

II. **Scope:** This procedure applies to Watson Pharmaceuticals', Inc. Physician Sampling Order Processing personnel and any other Watson personnel, directly of indirectly responsible for the fulfillment of non-controlled and controlled prescription drug sample requests via mail or common carrier and/or 3rd party fulfillment vendor and personnel.

DOCUMENT REFERENCES:	**Document Number**	**Document Title**
	N/A	**N/A**
ATTACHMENTS:	**Document Number**	**Document Title**
	Attachment A	Acknowledgement of Content (AOC)

DEFINITIONS:

•	Business Reply Card (BRC)	A card attached to the customer recall letter that is returned to the recall management firm stating what quantity or recalled/withdrawn product (response) is in their possession.
•	Prescription Drug Marketing Act (PDMA)	A law enacted in 1988 to establish restrictions and requirements relating to various aspects of human prescription drug marketing and distribution.
•	Sales Representative Sample Request Form	A form used by the Field Sales Rep to capture signatures for products that the physician requests. This form applies when regulations require samples to be mailed to the physician.
• **A**	Acknowledgement of Content (AOC)	A closed loop system used to verify that requested samples and the contents were delivered to the intended recipient.
•	Cycle Count Investigation Report (CCIR)	A form that is used to document overages, shortages and picking errors.
•	CCA	Corporate Complaint Administration Department
•	NTIS	National Technical Information Services
•	CSS	Customer Support Services

III. Procedure:

1.0 General

Responsibility **Action**

A Watson Pharma, Inc.

Call Center Operations
Call Center Operational Procedure

PROCEDURE:	**Sample Fulfillment**		
WRITTEN BY:	Judy Callahan	**DATE:**	May 3, 2004
Call Center Policy Number:	OPDCC 507509-02.00	**Policy Effective Date**	May 3, 2004

General

1.1 The Sales and Marketing department in conjunction with the Sales Operations department will develop specific business reply cards to be sent to licensed medical practitioners, soliciting product samples for promotion of Watson products.

1.2 The Prescription Drug Marketing Act (PDMA) requires specific information to be included on each Business Reply Card (BRC) and Sales Representative Sample Request form. Each written request (BRC) or Sales Representative Sample Request form will contain:

1.2.1 Name, address, professional designation and an original wet signature of the requesting practitioner.
1.2.2 Practitioner's State license number or authorization number.
1.2.3 Proprietary or established name, package size, quantity, and strength of product requested.
1.2.4 Name of manufacture and/or authorized distribution of record.
1.2.5 Name and address of the hospital or other health care entity to which the sample is delivered.
1.2.6 Date of request.
1.2.7 DEA # for controlled substance request
1.2.8 The verbiage "It is a federal offense to sell or offer to sell a drug sample. By signing this form, you certify that you will not seek payment from any patient or any third party payer for the samples requested hereunder"

1.3 It is Watson's policy to fulfill policies and requirements of the U.S. Food and Drug Administration (FDA) as they apply to the Prescription Drug Marketing Act (PDMA).

1.4 Call Center Operations/Order processing will have the overall responsibility of Watson's Business Reply and Sales Representative Sample Request mail program as it applies to fulfillment of the sample order requests, receipts and record retention.

1.5 CCA and Sample Accountability department must approve the design and content of all BRCs and Sales Representative Sample Request forms.

1.6 BRC requests will be developed with the return address of Watson's Corporate headquarters in Corona, CA. Any requests received at any other Watson facility will be forwarded to Physician Sample Order Processing in Corona, CA.

1.7 It is Watson's policy to not permit standing orders.

1.8 It is Watson's policy to not ship trade size product as samples.

2.0 BRC/Rep Request

Responsibility	**Action**
Order Processing	**2.1** Upon receipt of the BRCs/Rep Requests, Order Processing will visually inspect each card for accuracy and ensure that everything required as listed is completed correctly.
	2.2 Any requests that are not completely filled out with the required PDMA

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Call Center Operations
Call Center Operational Procedure

PROCEDURE:	**Sample Fulfillment**		
WRITTEN BY:	Judy Callahan	**DATE:**	May 3, 2004
Call Center Policy Number:	OPDCC 507509-02.00	**Policy Effective Date**	May 3, 2004

information will be rejected as invalid, and the practitioner or sales representative will be contacted via mail or telephone for the correct or missing information.

2.3 BRC requests and Sales Representative Sample Request Forms that have been visually inspected and are completed correctly can be prepared for processing.

2.3.1 The practitioner's state license number will be verified against the practitioner database supplied to Customer Call Center Operations from Sales Operations Department.

2.3.1.1 At least once a year, the Sales Operation Department will verify the aforementioned database to comply with PDMA regulation.

2.3.2 It is Watson Pharmaceuticals, Inc. policy to ship non-controlled sample products only to a facility that the requesting practitioner operates from. If the address of the licensed practitioner does not match the address of the practitioner's license, it is Watson Pharmaceutical's, Inc. policy to obtain a copy of A voided Rx from the physician as proof that this is a facility the practitioner is operating from.

2.3.3 The internet, using the State Board of Pharmacy website, may be used as a verification tool. If a practitioner can be verified against the state license database for non-controlled samples, the order processing clerk will print out the verified license information fro the internet and use as supporting documentation to process requests.

2.3.4 For controlled substances, the practitioner's DEA # will be verified against the current NTIS for the following:

2.3.4.1 Current DEA # and expiration date.

2.3.4.2 Registration for the applicable drug schedule

2.3.4.3 Shipment of samples only to the DEA registered address.

2.3.5 Watson's sample policy is to only ship quantities that meet Watson's monthly maximum quantity threshold within that month. Requests that exceed maximum monthly quantities will be rejected.

2.3.5.1 The maximum monthly quantity threshold is determined by script data and percent of market sampled. Sales Operations will have the responsibility of approving all maximum quantity threshold justifications.

3.0 Record Retention

Responsibility	**Action**	
General	**3.1**	Watson Pharmaceuticals, Inc. will retain all sample request forms and all receipts (AOCs) for a period of five (5) years.
Order Processing, Information Systems	**3.2**	Order processing in conjunction with the IS department will ensure that all records are maintained and easily retrievable upon request to the FDA or other regulatory agencies.

4.0 Diversion Detection Program

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Call Center Operations
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WRITTEN BY:	Judy Callahan	**DATE:**	May 3, 2004
Call Center Policy Number:	OPDCC 507509-02.00	**Policy Effective Date**	May 3, 2004

Responsibility	Action	
Sales OPS	**4.1**	A third party receives and scans all the controlled substance request forms generated by the sales representatives from the field. A random signature verification is performed on these forms, as well as call documents. Sample Accountability is responsible for reporting any negative, potential falsification of signature reports directly to CCA.
Call Center Operations	**4.2**	Non controlled BRC requests received at Watson Pharmaceuticals, Inc. will be randomly selected for signature verifications.
	4.2.1	Negative responses for all sample requests will be handled by Sales Operations and reported directly to CCA.

5.0 Loss Reporting

Responsibility	Action	
Sample Accountability/ Distribution Center	**5.1**	All loss in transit, damaged, stolen shipments, or significant loss of sample product are reported directly to the distribution center using the CCIR form, and then forwarded to Customer Service. In addition to the aforementioned incidences, falsification of records will require Sample Accountability to report all incidences to CCA.
Distribution Center	**5.2**	The distribution center is responsible for reporting loss in transit to the carrier as well as controlled product theft/losses to the DEA.
Sample Accountability	**5.3**	Investigation results will be forwarded to CCA for reporting to the FDA.

6.0 Acknowledgement of Content (AOC)

Responsibility	Action	
CSS	**6.1**	Watson Pharmaceuticals, Inc. has established a program to confirm that delivery has occurred to the requesting practitioner. This "closed loop" system is intended to verify that requested samples were actually delivered to the intended recipients and the contents of the delivery is verified against the packing slip. This system entails the following:
	6.1.1	The AOC, an additional document along with the packing slip, requests the practioner to verify content(s) of the delivery against the packing slip. The AOC will be added to every sample shipment.
	6.1.2	AOCs are returned to the Watson Pharmaceuticals, Inc. Corporate office.
Sample Fulfillment Group	6.1.3	The Watson Sample Fulfillment Group will track patters of non-response.
	6.1.3.1	Follow-up on non-responsive practitioners will be done via mail or telephone at scheduled intervals. If non-response goes past 120 days, the account is inactivated and can no

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PROCEDURE:	**Sample Fulfillment**		
WRITTEN BY:	Judy Callahan	**DATE:**	May 3, 2004
Call Center Policy Number:	OPDCC 507509-02.00	**Policy Effective Date**	May 3, 2004

longer receive samples. If at anytime after 120 days a signed letter is returned confirming delivery of the samples, the account will be reactivated.

A Watson Pharma, Inc.

Call Center Operations
Call Center Operational Procedure

PROCEDURE:	**Sample Fulfillment**		
WRITTEN BY:	Judy Callahan	**DATE:**	May 3, 2004
Call Center Policy Number:	OPDCC 507509-02.00	**Policy Effective Date**	May 3, 2004

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Call Center Operations
Call Center Operational Procedure

PROCEDURE:	**Sample Fulfillment**		
WRITTEN BY:	Judy Callahan	**DATE:**	May 3, 2004
Call Center Policy Number:	OPDCC 507509-02.00	**Policy Effective Date**	May 3, 2004

A Watson Pharma, Inc.

Call Center Operations
Call Center Operational Procedure

PROCEDURE:	**Suspicious Orders of Controlled Drugs**		
WRITTEN BY:	Judy Callahan	**DATE:**	May 3, 2004
Call Center Policy Number:	OPDCC 507509-03.00	**Policy Effective Date**	May 3, 2004
REVISION WRITTEN BY:		**REVISION DATE:**	
Supersede CC Policy #	CC 1007.00	**CC Policy Date:**	09/03
cSOP Reference #	cSOP 11-004	**cSOP Ref. Date:**	May 3, 2004

I. **Purpose:** To assure distribution of controlled drugs is monitored for excessive use by an individual location using the DEA number as the identifier.

II. **Scope:** This procedure applies to all controlled drugs distributed by Watson Laboratories, Inc. and its Subsidiaries.

DOCUMENT REFERENCES:

Document Number	Document Title
CTMAN-80-041-CC-OPR	Order Processing
CTMAN-80-041-CC-OPS	Order Processing Supervisor

ATTACHMENTS:

Document Number	Document Title
N/A	N/A

DEFINITIONS:

•	DEA	Drug Enforcement Agency
• **A**	SOMS	Suspicious Order Management System

III. Procedure:

1.0 Process for Suspicious Orders of controlled drugs

Responsibility	Action	
General	**1.1**	The SAP system compiles a past history of controlled substance drug product orders by each customer to establish a normal order size and order frequency. This is accomplished through the normal Sales Order process see CTMAN-80-041-CC-OPR, Order Processing, for details on this process.
Call Center Management/ Controlled Substance Compliance Management	**1.2**	The SOMS Multiplier Table is determined by Call Center Management and the Controlled Substance Compliance Department.

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Call Center Operations
Call Center Operational Procedure

PROCEDURE:	**Suspicious Orders of Controlled Drugs**		
WRITTEN BY:	Judy Callahan	**DATE:**	May 3, 2004
Call Center Policy Number:	OPDCC 507506-03.00	**Policy Effective Date**	May 3, 2004

	1.2.1	See CTMAN 80-045-CC-LEM, License Entry and Management for description of system functionality with regards to the establishment of SOM levels, as well as how to access this information.
Order Processing Representative	**1.3**	The list is to be updated by written request to the customer approximately 30 days prior to the expiration date of the current registrations.
License Administrator	**1.4**	The license administrator will review the SOMS report, and then contact the customer to confirm the quantity ordered and verify the reason for a larger or more frequent order.
	1.5	Once this SOMS report is confirmed and verified by the Customer, the SOMS report is signed and marked with a reason code by the license administrator and submitted to the Supervisor or Management for review and signature.
	1.6	The license administrator will be responsible to ensure that pending sales orders on hold due to suspicious order (SOMS) violation are investigated.
	1.7	The license administrator will release pending orders due to SOMS violations by canceling the order, or reducing the quantity, per customer requirements.
	1.8	If the SOMS violation cannot be resolved by canceling the order or reducing the quantity, the license administrator will escalate the suspicious order to the next level.
	1.9	Determine if the order does or does not classify as suspicious.
	1.10	If a valid reason (based on objective criteria) does not exist, the order will be deemed as a suspicious order and will not be filled. Report suspicious issue to Control Substance Compliance Department.
Controlled Substance Compliance Department	**1.11**	The control Substance Compliance Department will determine the next level of Communication.
Order Processing Representative	**1.12**	File a copy of the SOMS Report, along with the customer purchase order, in the suspicious order record file.

A Watson Pharma, Inc.

Call Center Operations
Call Center Operational Procedure

PROCEDURE:	**Process Controls for Sale & Distribution of Pharmaceutical Products**		
WRITTEN BY:	Judy Callahan	**DATE:**	May 3, 2004
Call Center Policy Number:	OPDCC 507509-04.00	**Policy Effective Date**	May 3, 2004
REVISION WRITTEN BY:		**REVISION DATE:**	
Supersede CC Policy #	CC 1005.00	**CC Policy Date:**	09/03
cSOP Reference #	cSOP 11-002	**cSOP Ref. Date:**	May 3, 2004

I. **Purpose:** To establish procedures for the receipt, processing, and invoicing of Sales Orders.

II. **Scope:** This procedure applies to Sales Order Processing functions within the Call Center. It applies to Sales Orders received electronically through SAP system functionality as well as Sales Orders entered manually.

DOCUMENT REFERENCES:

Document Number	Document Title
CSOP 11-003	DEA License Verification
CSOP 11-003	Suspicious Orders of Controlled Drugs
CSOP 14-026	Returned and Salvaged Goods
CTMAN-80-041-CC-OPS	Order Processing
CTMAN-80-047-CC-OPS	Order Processing Supervisor

ATTACHMENTS:

Document Number	Document Title
N/A	N/A

DEFINITIONS:

•	EDI	Electronic Data Interchange
• **A**	CSR	Customer Service Representative
•	CMA	Customer Master Administrator
•	CSS	Customer Support Services
•	SO	Sales Order
•	SOP (Call Center)	Sample Order Processing
•	VMI	Vendor Managed Inventor

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Call Center Operations
Call Center Operational Procedure

PROCEDURE:	**Process Controls for Sale and Distribution of Pharmaceutical Products**		
WRITTEN BY:	Judy Callahan	**DATE:**	May 3, 2004
Call Center Policy Number:	OPDCC 507509-04.00	**Policy Effective Date**	May 3, 2004

III. Procedure:

1.0 Customer Master Records

Responsibility	**Action**	
Customer Master Administrator	**1.1**	The following are prerequisites for the initial set up of an account in the SAP System:
	1.1.1	New customer requests require management approval prior to creating a customer master record.
	1.1.2	New customer requests require financial review and approval prior to creating a customer master record.
	1.1.3	Customer Service will be notified when a request to add a new customer is created.
	1.1.4	New customer EDI setup requires communication to Management of Call Center Operations.
	1.2	The following are prerequisites for the initial set up of an account in the SAP System:
	1.2.1	Open orders shall be identified before deactivating an account.
	1.2.2	Written notification will be sent to Customer Support Services, Contract Operations, Telesales and Accounts Receivable when maintenance is performed.
	1.2.3	Supervisor/Manager authorization is required on customer master record changes or material exclusions, dating requirements, backorder limit, terms, partner functions, exclusions, block status.
	1.2.4	Customer Master record changes of terms, partner functions, delivery priority, dating requirements and exclusions require approval of a Supervisor.
	1.2.5	Customer Master Sales Order/Delivery Block requires Management approval.
	1.2.6	Customer Master Mass Change requires Management approval.
	1.2.7	Marketing determines material/customer mass cancellations. Call Center operations Management approval is required.

2.0 Processing Sales Orders

Responsibility	**Action**	
Order Processing Representative	**2.1**	A Sales Order is created in SAP either electronically (through EDI and VMI) or manually. See CTMAN 80-041-CC-OPR for details on system processes.
	2.2	The Sales Orders are then checked against specific criteria.
	2.2.2	Any order in violation will be system blocked. The Rep will address each block and determine if corrective actions are required such as editing the order information or blocking/unblocking the order See

CTMAN 80-041-CC-OPR, Order Processing. The types of criteria that are system validated include:

2.2.2.1 The order must be checked to ensure the customer has a valid DEA or State License.

2.2.2.2 The order must be checked to ensure that the customer's DEA License covers the class of material that the customer may purchase including Schedule 2 controlled substances. If there are any discrepancies see CSOP 11-003, DEA Registration Verification. If the material on order is an Rx but not a controlled substance, and the record does not identify a DEA# the system will check for a State License.

2.2.2.4 The order is verified to make sure the allocated inventory meets customer dating requirements.

2.2.2.5 The pricing of the product will be verified.

2.2.2.6 Customer credit limits will be checked.

2.2.2.7 Backorder processing may be executed if allowed.

2.3 Once all of the above criteria have been checked and any blocks are resolved, the order is unblocked.

2.4 The order is re-verified to ensure that no status changes have occurred. See CTMAN 80-041-CC-OPR, Order Processing.

2.5 Order confirmations are created. See CTMAN 80-041-CC-OPR, Order Processing.

3.0 Order Processing Management

Responsibility	Action	
Order Processing Supervisor	**3.1**	The Order Processing Supervisor can enable maintenance of open Sales Orders on Backorder. See CTMAN 89-041-CC-OPS Order Processing Supervisor Procedural controls around backorders include:
Order Processing Supervisor/ CSR	3.1.1.	The Order processing Supervisor authorizes the CSR to manually cancel backorders by customer request for ship-to locations that have closed or relocated.
Order processing Supervisor	3.1.2	The Order processing Supervisor authorizes the CSR to contact the customer for revised dating requirements for backordered line items.
	3.1.3	Marketing requests Order Processing to cancel or future date backorders by material or customer.
	3.1.4	Mass changes of backorders for product substitution, pricing, plant reroute that require direction from Marketing and Call Center Management approval.
Sample Order Processing	3.1.5	The SOP (Sample Order Processing) department will also determine which sample orders will be retained as backorders.
Order	**3.2**	The Order Processing Supervisor can modify the sample order process to

A Watson Pharma, Inc.

Call Center Operations
Call Center Operational Procedure

PROCEDURE:	**Process Controls for Sale and Distribution of Pharmaceutical Products**		
WRITTEN BY:	Judy Callahan	**DATE:**	May 3, 2004
Call Center Policy Number:	OPDCC 507509-04.00	**Policy Effective Date**	May 3, 2004

Processing Supervisor		meet business requirements. Sample Order Maintenance functions include: 3.2.1 Setting of Maximum quantities for Sample Orders for specific customers, as determined and approved by Marketing. 3.2.2 Setting of Materials approved for Sample Orders, as determined by Marketing. 3.2.3 Field Sales Support may also provide a file of state/title exclusion records for Sample Orders.
Customer Master Administrator	**3.3**	The CMA can select Delivery Block/Unblock customers for CSS management approval. See OPD 80-041-CC-OPR, Order Processing
Order Processing Supervisor		3.3.1 The Order Processing Supervisor, upon approval, can block/unblock the delivery. See OPD 80-047-CC-OPR, Order Processing Supervisor.
	3.4	Order Processing Supervisor to review/approve RE order types with delivery block.

4.0 Invoicing

Responsibility	**Action**	
Order Processing Representative	**4.1**	An SAP system process to release shipped inventory and generate invoices is conducted on a daily basis, (For orders received electronically a batch process is automatically executed at the end of the day) See CTMAN-80-041-CC-OPR, Order Processing.

Call Center Training Signature Log

Course Information			
Document #:	**Title:**	**Date of Event**	**Length of Event (hours)**
OPDCC 507509-01.00 OPDCC 507509-02.00 OPDCC 507509-03.00 OPDCC 507509-04.00	DEA Registration Verification Sample Fulfillment Suspicious Order of Controlled Drugs Process Controls for Sales & Distribution of Pharmaceutical Product		90 minutes

Facilitator Information		
Facilitator / Trainer Name	Facilitator / Trainer Signature	Emp. ID#
Facilitator / Trainer Title	Facilitator / Trainer Department or Company	

Describe training event (required)

Training held via conference call or at Watson site. All Call Center personnel trained on the documents listed above to ensure all are compliant with Watson standard operating procedures, department policy and DEA Regulations as it pertains to the matter above.

Describe method used for assessment (required)

Q&A

Attendees

	Print Name	Employee I.D. #	Department	Signature
1.				
2.				
3.				
4.				
5.				
6.				
7.				
8.				
9.				
10.				

DISTRIBUTION:
Original remain on site
Cc the following:

Suzette Guzman – Corona
Joanne Wobeser – Morristown
Ella David – Glenview
Xerox copy of ALL training sent to Call Center Operation Trainer

Call Center Training & Development
Effective 08/03/2004

Call Center Training Signature Log

Page ___of____

Course Information			
Document #:	**Title:**	**Date of Event**	**Length of Event (hours)**
OPDCC 507509-01.00 OPDCC 507509-02.00 OPDCC 507509-03.00 OPDCC 507509-04.00	DEA Registration Verification Sample Fulfillment Suspicious Order of Controlled Drugs Process Controls for Sales & Distribution of Pharmaceutical Product		90 minutes

11.				
12.				
13.				
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DISTRIBUTION:
Original remain on site
Cc the following:
Suzette Guzman – Corona
Joanne Wobeser – Morristown
Ella David – Glenview
Xerox copy of ALL training sent to Call Center Operation Trainer

Call Center Training & Development
Effective 08/03/2004

A Watson Pharma, Inc.

Call Center Operations - Operational Procedure

PROCEDURE:	**Complaints and Medical Inquiries**		
WRITTEN BY:	Eileen Mesis	**DATE:**	July 27, 2004
Call Center Policy Number:	OPDCC 507509-05.00	**Policy Effective Date**	September, 2003
REVISION WRITTEN BY:	Eileen Mesis	**REVISION DATE:**	September 22, 2004
Supersede CC Policy #	CC – 1008.02	**CC Policy Date:**	July 27, 2004
cSOP Reference #	cSOP # 09-052 Potential Sources for Complaints cSOP # 09-056 Handling Medical Inquiries	**cSOP Ref. Date:**	01/30/04 09/23/03

I. **Purpose:** To assure all drugs product complaints and medical inquiries are routed to the appropriate department to ensure compliance with the requirements of Good Manufacturing Practice and also to provide efficient and professional service to the inquirer.

II. Scope:

DEFINITIONS:

Adverse Events (AE)

Quality Defect
This procedure applies to all drug product complaints and medical inquiries communicated through Watson Laboratories, Inc. and its subsidiaries, Customer Service Representatives as well as any out source Call Center entities.

A report of an adverse event or quality defects

Any adverse event associated with the use of a drug in humans, whether or not considered product-related, including the following: An adverse event occurring in the course of the use of a drug product in professional practice; an adverse event occurring from drug overdose whether accidental or intentional; an adverse event occurring from drug abuse; an adverse event occurring from drug withdrawal; and any failure of expected pharmacological action. Reporting an adverse experience does not necessarily reflect a conclusion by the applicant or the FDA that the product caused or contributed to the adverse experience. Examples: person experienced nausea while taking the drug: it seemed like the drug did not work.

Any reported problem with the material proprieties of the finished pharmaceutical product or its packaging.
Ex: broken tablets, patch adhesion failure, packaging problem, or issue with labeling.

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Call Center Operations - Operational Procedure

PROCEDURE:	**Complaints and Medical Inquiries**		
WRITTEN BY:	**Eileen Mesis - Manager**	**DATE:**	June 19, 2003
Call Center Policy Number:	<Policy number >	**Policy Effective Date**	

Medical Inquiry

Medical Communications Coordinator (MCC)

CSR

*A request for information regarding a drug product without an expression of dissatisfaction regarding any attribute of the product. An inquiry may consist of, but not be limited to the following: perservatives, storage, active/inactive ingredients, and product identification requests, or any other information contained in the product package insert or medical literature. A request for information regarding a drug product without an expression of dissatisfaction regarding any attribute of the product. An inquiry may consist of, but not be limited to the following: perservatives, storage, active/inactive ingredients, and product identification requests, or any other information contained in the product package insert or medical literature.A request for information regarding a drug product without an expression of dissatisfaction regarding any attribute of the product. An inquiry may consist of, but not be limited to the following: perservatives, storage, active/inactive ingredients, and product identification requests, or any other information contained in the product package insert or medical literature.*A request for information regarding a drug product without an expression of dissatisfaction regarding any attribute of the product. An inquiry may consist of, but not be limited to the following: preservatives, storage, active/inactive ingredients, and product identification requests, or any other information contained in the product package insert or medical literature.

Assigned person of the Medical Communication department that assists with the processing and handling of incoming calls.

Customer Service Representative

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Call Center Operations - Operational Procedure

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WRITTEN BY:	**Eileen Mesis - Manager**	**DATE:**	June 19, 2003
Call Center Policy Number:	<Policy number >	**Policy Effective Date**	

Call Center Operations		**Background:** Pharmaceutical companies are mandated by the FDA to have a complaint system in place. Medical inquiries must be in place to provide efficient and professional service to the inquirer and capture product complaint intertwine with the inquiries. **MEDICAL INQUIRIES** **1.0** **Note: If communication relays a complaint and a medical inquiry, follow procedures starting with section 2.0 'COMPLAINTS'** **Live Phone Call Received:** When a caller identifies a medical inquiry with a Watson product, call Medical Communications ext. 8398 **HOTLINE**(973-355-8399) and identify yourself as a Watson **1.1** employee; relay the nature of the call and all available information, then, if possible, connect the phone call live. Personnel from Medical Communications, a Medical Communications Coordinator (MCC), will receive the call. In the event that a live person is not available, document all available information provided by caller (callers name, contact information, product information and reason for contact) and fax, in a timely fashion to: **Medical Communications** **Phone: ext. 8398 or** **Fax: (973)355-8594 *using new Interdepartmental form** ***See Exhibit B** **ATTN: Medical Communications** **All drug product complaints should be handled as per section 2.1** ***Note in the event of a selective power outage or interruption of phone service, document caller contact information and all information caller has provided; email may be used as a backup method of communication to be immediately followed by notification to Medical Communications via fax and phone upon resolution of the selective power outage or interruption of phone service.**

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Call Center Operations - Operational Procedure

PROCEDURE:	**Complaints and Medical Inquiries**		
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Call Center Policy Number:	<Policy number >	**Policy Effective Date**	

Voicemail message received:

1.1.1 If a voicemail message is received where the caller identifies a medical inquiry with a Watson product, document all available information provided by caller (callers name, contact information, product information and reason for contact) and fax in a timely fashion:

Medical Communications
Phone: ext. 8398 or
Fax: (973)355-8594 *using new Interdepartmental form
***See Exhibit B**
ATTN: Medical Communications

1.1.2 **Documentation Received by Fax:**

If a fax is received which identifies a medical inquiry with a Watson product, document all available information provided and fax along with the original

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Call Center Operations - Operational Procedure

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WRITTEN BY:	**Eileen Mesis - Manager**	**DATE:**	June 19, 2003
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		1.1.3	fax received in a timely fashion to: **Medical Communications** **Phone: ext. 8398 or** **Fax: (973)355-8594 *using new Interdepartmental form** ***see Exhibit B** **ATTN: Medical Communications** **Documentation received by mail:** If mail is received which identifies a medical inquiry with a Watson product, document all available information provided by writer, send via interoffice mail along with the original mail received in a timely fashion to: **Medical Communications Coordinator** **2nd Floor** **Morristown, New Jersey**
			***Medical inquiries for Over-The-Counter products (other than Nicotine Gum) are forwarded to the manager, Quality Assurance/Regulatory Affairs, OTC Products. Calls regarding Nicotine Gum are handled as above.**

A Watson Pharma, Inc.

Call Center Operations - Operational Procedure

PROCEDURE:	**Complaints and Medical Inquiries**		
WRITTEN BY:	**Eileen Mesis - Manager**	**DATE:**	June 19, 2003
Call Center Policy Number:	<Policy number >	**Policy Effective Date**	

COMPLAINTS

Customer Service Representative

2.0 *Live Phone Calls Received* Live Phone Calls Received

2.1 ***For live phone calls, Customer Service and Company Receptionist will follow the guidelines, which states: for phone calls where caller identifies an adverse event or quality defect, connect phone call and relay any information provided to ext. 4395 HOTLINE (951-493-4395) OR ext. 4444 HOTLINE (951-493-4444) . Personnel from either Drug Safety (ext. 4395 Hotline) or Corporate Quality Complaint Operations (ext. 4444 Hotline) will receive the call. Calls may be connected into voicemail if live personnel are unavailable.***

If for any reason it is not possible to connect call, ex: mail box full, customer insists on live person, and a live person is not available, take caller's name, address, phone number, and all information caller has provided and forward this information immediately (within 24-hours) by fax and phone to:

DRUG SAFETY

Phone: ext. 4399 (951-493-4399)
Fax: (951) 493-5825 or
(951)493-5815
***using new Interdepartmental form**
***see Exhibit B**
ATTN: Adverse Events/Complaints

When calling, identify yourself as a Watson employee or representative. When faxing, include your name and phone number on paperwork.

Drug Safety has instructed customer service to forward all phone calls to ext. 4395 (Drug Safety Hotline) or ext 4444

(CQCO Hotline). If all lines are busy, the caller will automatically go into voicemail. If all Drug Safety lines are busy or unavailable, and the caller still insists on speaking with someone, the call should be forwarded to a Drug Safety Manager. Calls are not to be left in Drug Safety Manager's voice mail. See Exhibit A for contact listing.

***Note in the event of a selective power outage or interruption of phone service, document caller contact information and all information caller has provided; email may be used as a backup method of communication to be immediately followed by notification to Drug Safety via fax and phone upon resolution of the selective power outage or interruption of phone service.**

3.0 Documentation Received by E-Mail

3.1 If an e-mail is received which identifies that an adverse event or quality defect has or may have occurred, notify Drug Safety immediately (within 24 hours) by phone AND fax (fax printed e-mail) to:

DRUG SAFETY
Phone: ext. 4399
Fax: (951) 493-5825 or (951) 493-5815
***using new Interdepartmental form**
***See Exhibit B**
ATTN: Adverse Events/Complaints

When calling, identify yourself as a Watson employee or representative. When faxing, include your name and phone number on the paperwork.

4.0 Product Sample Received

4.1 If a product sample is received along with information

indicating that an adverse event or quality defect has or may have occurred, forward the sample and accompanying paperwork by trackable mail, within 2 business days of receipt, to:

Watson Laboratories, Inc.
ATTN: Corporate Quality Complaint Operations
311 Bonnie Circle
Corona, CA 92880
AND RELAY INFORMATION by phone within 24 hours of receipt to:
Corporate Quality Complaint Operations
Phone: ext. 4445

When calling, identify yourself as a Watson employee or representative. When forwarding product sample, include the original packaging, if possible, and include your name and phone number and the complainant name address and phone number.

If a product sample is received along with information indicating that an adverse event or quality defect has or may have occurred, forward the sample and accompanying paperwork by trackable mail, within 2 business days of receipt to:

5.0

*Voice Mail Messages Received***Voice Mail Message Received**

5.1 If voicemail message is received (applies to switch board as well) where the caller identifies that an adverse event or quality defect has or may have occurred, transfer voicemail message to ext. 4399 (951-493-4399) OR ext. 4445 (951-493-4445). If for any reason it is not possible to transfer, transcribe all information caller has provided and forward this information immediately (within 24 hours), by fax AND phone to:

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Call Center Operations - Operational Procedure

PROCEDURE:	**Complaints and Medical Inquiries**		
WRITTEN BY:	**Eileen Mesis - Manager**	**DATE:**	June 19, 2003
Call Center Policy Number:	<Policy number >	**Policy Effective Date**	

DRUG SAFETY

Phone: ext. 4399 or (951)493-4399
Fax: (951) 493-5825 or
(951)493-5815 *using new Interdepartmental form
***see Exhibit B**
ATTN: Adverse Events/ Complaints

When calling, identify yourself as a Watson employee or representative. When faxing, include your name and phone number.

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PROCEDURE:	**Complaints and Medical Inquiries**		
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Customer Service Representative

6.0 *Documentation Received by Fax*Documentation Received by Fax

6.1 ***If a fax is received which identifies that an adverse event or quality defect has or may have occurred, forward this information immediately (within 24 hours), by fax AND phone to:***

DRUG SAFETY

Phone: ext. 4399
Fax: (951) 493-5825 or
(951)493-5815 *using new Interdepartmental form
***see Exhibit B**
ATTN: Adverse Events/ Complaints

7.0 When calling, identify yourself as a Watson employee or representative. When faxing, include your name and phone number on the paperwork.

Documentation received by Mail

If mail is received which identifies that an adverse event or quality defect has or may have occurred, forward this information immediately (within 24 hours), by interoffice mail AND phone to:

DRUG SAFETY

Phone: ext. 4399

Interoffice to: Drug Safety –

ATTN: Adverse Events/Complaints

When calling, identify yourself as a Watson employee or

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WRITTEN BY:	**Eileen Mesis - Manager**	**DATE:**	June 19, 2003
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representative. When forwarding letter, include the envelope, packaging, etc. When it is not possible to forward the original letter received, copy and fax to:

Fax (951)493-5825 or

(951) 493-5815 (using new Interdepartmental form *see Exhibit B

ATTN: Adverse Events/Complaints

If mail is received which identifies that an adverse event or quality defect has or may have occurred, forward this information immediately (within 24 hours), by fax AND phone, to:

***Complaints for Over-The-Counter products (other than Nicotine Gum) are forwarded to the manager, Quality Assurance/Regulatory Affairs, OTC Products. Complaints regarding Nicotine Gum are handled as above.**

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Call Center Operations - Operational Procedure

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SUMMARY OF CHANGES

CC NUMBER	REVISION NUMBER	EFFECTIVE DATE	ISSUE DATE	SUMMARY
CC-1202.02	CC1008.01	09/2003	09/2003	Revision: Changed from General Department Policy to Department cSOP Policy Revision adding Medical Communications cSOP 4/2004 Revision adding new Interdepartmental fax form Exhibit B 7/2004
CC-1008.01	CC-1008.02	07/2004	07/2004	Revision: Department policy updated and revised to comply with corporate policy and procedure.

A Watson Pharma, Inc.

Call Center Operations
Call Center Operational Procedure

PROCEDURE:	**Process Controls for Sale & Distribution of Pharmaceutical Products**		
WRITTEN BY:	Judy Callahan	**DATE:**	May 3, 2004
Call Center Policy Number:	OPDCC 507509-04.00	**Policy Effective Date**	May 3, 2004
REVISION WRITTEN BY:		**REVISION DATE:**	
Supersede CC Policy #	CC 1005.00	**CC Policy Date:**	09/03
cSOP Reference #	cSOP 11-002	**cSOP Ref. Date:**	May 3, 2004

I. **Purpose:** To establish procedures for the receipt, processing, and invoicing of Sales Orders.

II. **Scope:** This procedure applies to Sales Order Processing functions within the Call Center. It applies to Sales Orders received electronically through SAP system functionality as well as Sales Orders entered manually.

DOCUMENT REFERENCES:

Document Number	Document Title
CSOP 11-003	DEA License Verification
CSOP 11-003	Suspicious Orders of Controlled Drugs
CSOP 14-026	Returned and Salvaged Goods
CTMAN-80-041-CC-OPS	Order Processing
CTMAN-80-047-CC-OPS	Order Processing Supervisor

ATTACHMENTS:

Document Number	Document Title
N/A	N/A

DEFINITIONS:

•	EDI	Electronic Data Interchange
• **A**	CSR	Customer Service Representative
•	CMA	Customer Master Administrator
•	CSS	Customer Support Services
•	SO	Sales Order
•	SOP (Call Center)	Sample Order Processing
•	VMI	Vendor Managed Inventor

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Call Center Operations
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PROCEDURE:	**Process Controls for Sale and Distribution of Pharmaceutical Products**		
WRITTEN BY:	Judy Callahan	**DATE:**	May 3, 2004
Call Center Policy Number:	OPDCC 507509-04.00	**Policy Effective Date**	May 3, 2004

III. Procedure:

1.0 Customer Master Records

Responsibility	**Action**	
Customer Master Administrator	**1.1**	The following are prerequisites for the initial set up of an account in the SAP System:
	1.1.1	New customer requests require management approval prior to creating a customer master record.
	1.1.2	New customer requests require financial review and approval prior to creating a customer master record.
	1.1.3	Customer Service will be notified when a request to add a new customer is created.
	1.1.4	New customer EDI setup requires communication to Management of Call Center Operations.
	1.2	The following are prerequisites for the initial set up of an account in the SAP System:
	1.2.1	Open orders shall be identified before deactivating an account.
	1.2.2	Written notification will be sent to Customer Support Services, Contract Operations, Telesales and Accounts Receivable when maintenance is performed.
	1.2.3	Supervisor/Manager authorization is required on customer master record changes or material exclusions, dating requirements, backorder limit, terms, partner functions, exclusions, block status.
	1.2.4	Customer Master record changes of terms, partner functions, delivery priority, dating requirements and exclusions require approval of a Supervisor.
	1.2.5	Customer Master Sales Order/Delivery Block requires Management approval.
	1.2.6	Customer Master Mass Change requires Management approval.
	1.2.7	Marketing determines material/customer mass cancellations. Call Center operations Management approval is required.

2.0 Processing Sales Orders

Responsibility	**Action**	
Order Processing Representative	**2.1**	A Sales Order is created in SAP either electronically (through EDI and VMI) or manually. See CTMAN 80-041-CC-OPR for details on system processes.
	2.2	The Sales Orders are then checked against specific criteria.
	2.2.2	Any order in violation will be system blocked. The Rep will address each block and determine if corrective actions are required such as editing the order information or blocking/unblocking the order See

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Call Center Operations
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CTMAN 80-041-CC-OPR, Order Processing. The types of criteria that are system validated include:

2.2.2.1 The order must be checked to ensure the customer has a valid DEA or State License.

2.2.2.2 The order must be checked to ensure that the customer's DEA License covers the class of material that the customer may purchase including Schedule 2 controlled substances. If there are any discrepancies see CSOP 11-003, DEA Registration Verification. If the material on order is an Rx but not a controlled substance, and the record does not identify a DEA# the system will check for a State License.

2.2.2.4 The order is verified to make sure the allocated inventory meets customer dating requirements.

2.2.2.5 The pricing of the product will be verified.

2.2.2.6 Customer credit limits will be checked.

2.2.2.7 Backorder processing may be executed if allowed.

2.3 Once all of the above criteria have been checked and any blocks are resolved, the order is unblocked.

2.4 The order is re-verified to ensure that no status changes have occurred. See CTMAN 80-041-CC-OPR, Order Processing.

2.5 Order confirmations are created. See CTMAN 80-041-CC-OPR, Order Processing.

3.0 Order Processing Management

Responsibility	**Action**	
Order Processing Supervisor	**3.1**	The Order Processing Supervisor can enable maintenance of open Sales Orders on Backorder. See CTMAN 89-041-CC-OPS Order Processing Supervisor Procedural controls around backorders include:
Order Processing Supervisor/ CSR		3.1.1. The Order processing Supervisor authorizes the CSR to manually cancel backorders by customer request for ship-to locations that have closed or relocated.
Order processing Supervisor		3.1.2 The Order processing Supervisor authorizes the CSR to contact the customer for revised dating requirements for backordered line items.
		3.1.3 Marketing requests Order Processing to cancel or future date backorders by material or customer.
		3.1.4 Mass changes of backorders for product substitution, pricing, plant reroute that require direction from Marketing and Call Center Management approval.
Sample Order Processing		3.1.5 The SOP (Sample Order Processing) department will also determine which sample orders will be retained as backorders.
Order	**3.2**	The Order Processing Supervisor can modify the sample order process to

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Processing Supervisor

meet business requirements.
Sample Order Maintenance functions include:

3.2.1 Setting of Maximum quantities for Sample Orders for specific customers, as determined and approved by Marketing.

3.2.2 Setting of Materials approved for Sample Orders, as determined by Marketing.

3.2.3 Field Sales Support may also provide a file of state/title exclusion records for Sample Orders.

Customer Master Administrator

3.3 The CMA can select Delivery Block/Unblock customers for CSS management approval. See OPD 80-041-CC-OPR, Order Processing

Order Processing Supervisor

3.3.1 The Order Processing Supervisor, upon approval, can block/unblock the delivery. See OPD 80-047-CC-OPR, Order Processing Supervisor.

3.4 Order Processing Supervisor to review/approve RE order types with delivery block.

4.0 Invoicing

Responsibility	**Action**	
Order Processing Representative	**4.1**	An SAP system process to release shipped inventory and generate invoices is conducted on a daily basis, (For orders received electronically a batch process is automatically executed at the end of the day) See CTMAN-80-041-CC-OPR, Order Processing.

